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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/768,742	01/23/2001	Ewald A. Terpetschnig	LJL 32901	3871

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EXAMINER

LAM, ANN Y

ART UNIT PAPER NUMBER

1641

DATE MAILED: 09/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

SM

Office Action Summary

Application No.

09/768,742

Applicant(s)

TERPETSCHNIG ET AL.

Examiner

Ann Y. Lam

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 June 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 28-30,33-41 and 83-89 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 28-30,33-41 and 83-89 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>9/24/01</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 28-30, 33-41 and 83-89 are rejected under 35 U.S.C. 102(e) as being anticipated by Kopf-Sill et al., 6,524,790.

As to claim 83, Kopf-Sill discloses a kit comprising a probe (e.g., first reactant, see column 30, lines 31-46) bound to a member (i.e., the moiety, see column 30, lines 36-46), where the member is a compound (e.g., receptor, see column 30, line 36) that specifically binds to an analyte (e.g., ligand, see column 30, line 36), or is a substrate (see column 30, line 36) for the analyte (e.g., enzyme, see column 30, line 36); and a particulate mass label (see column 28, lines 4-5) capable of specifically binding to the member, the complex formed by binding of the member to the analyte, or the product of the action of the analyte on the member; wherein a measurable property of the probe is sensitive to the size of the complex formed by binding of the mass label, probe, and the member, member-analyte complex, or member product (see column 32, line 47 – column 33, line 6, and column 34, lines 11-26.)

As to claims 84 and 85, the particulate mass label is a glass bead (see column 34, line 61.)

As to claim 86, the particulate mass label is a colloidal metal or a nanocrystal (see column 28, line 5.)

As to claim 87, the analyte is an enzyme, and the probe is bound to a member that is a substrate for the enzyme (see column 32, line 51.)

As to claim 88, the measurable property of the probe is different for the probe bound to the enzyme substrate than for the complex of the probe, the member product and the mass label (see column 32, line 64 – column 33, line 6, and column 34, lines 11-26.)

As to claim 89, the measurable property may be measured using fluorescence polarization (see column 28, lines 1-6.)

As to claim 28, the probe is photoluminescent (see column 28, lines 1-6.)

As to claim 29, the probe is capable of having a photoluminescence lifetime that is greater than the rotational correlation time of the unbound probe and less than the rotational correlation time of the complex formed by binding of the probe, member or member product, and mass label (see column 28, lines 1-6, and lines 29-37.)

As to claim 30, the probe binds to the member noncovalently (e.g. antibody-antigen binding, see column 30, lines 36-41.)

As to claim 33, the mass label (bead, column 34, lines 52-55) is capable of specifically binding to more than one member.

As to claim 34, the mass label being a first mass label, further comprising a second mass label capable of specifically binding to at least one of the member, the complex formed by binding of the probe to the member, the member product, and the first mass label, but not the probe alone (see column 28, lines 38-44, and lines 52-55.)

As to claim 35, the second mass label is capable of specifically binding to at least two first mass labels, so that the second mass label may form crosslinks between members (see column 28, lines 38-44 and lines 52-55.)

As to claim 36, the second mass label includes at least one of the following: avidin, biotin, lectin, sugar, and an immunological binding partner (see column 28, line 47.)

As to claim 37, the probe is not normally present in the sample (see column 32, lines 31-34.)

As to claim 38, the mass label is not normally present in the sample (see column 32, lines 31-34.)

As to claim 39, the property of the probe is related to a rotational diffusion coefficient of the probe (see column 28, lines 1-6, and lines 29-37.)

As to claim 40, the property may be measured using a technique selected from the group consisting of polarization, light scattering, and magnetic resonance (see column 29, lines 9-28, and column 32, line 64 – column 33, line 6.)

As to claim 41, the property of the probe is related to the translational diffusion coefficient of the probe (see column 29, lines 9-28, and column 32, line 64 – column 33, line 6.)

Response to Arguments

Applicant's arguments filed June 17, 2004 have been fully considered but they are not persuasive.

Applicant argues on page 11, last line, that Kopf-Sill does not disclose a "particulate mass label" distinct from the probe, that binds specifically to one of the reactant or product.

In response, Examiner re-asserts that Kopf-Sill discloses a particulate mass label (see column 28, lines 4-5) capable of specifically binding to the member, the complex formed by binding of the member to the analyte, or the product of the action of the analyte on the member. More specifically, Kopf-Sill discloses a label that is coupled directly or indirectly to a component of the assay (column 28, lines 4-8, the component of the assay being equivalent to the claimed "member" or "complex"; see also column 28, lines 14-20 and lines 29-31, for examples of a label coupled to a molecule, the molecule being equivalent to the claimed "member".)

Applicant also argues on top of page 12 that Kopf-Sill does not disclose a "probe" having a measurable property that is sensitive to the size of a complex formed by binding of a mass label and one of the reactant and product, but instead discloses merely a marker, such as a fluorophore, to assay an existing, measurably distinct characteristic of reactant and product, without further modification or reaction.

In response, Examiner re-asserts that Kopf-Sill discloses a probe (e.g., first reactant, see column 30, lines 31-46) having a measurable property that is sensitive to

the size of the complex formed by binding of the mass label, probe, and the member, member-analyte complex, or member product, as claimed by Applicant, since the binding of the mass label, probe and member (or member-analyte complex or member product), will necessarily change the size of the complex, the size of the complex being a measurable property.

Moreover, in response to Applicant's argument on page 12, with respect to claims 89 and 29, that Kopf-Sill fails to even mention fluorescence polarization, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). In this instance, Kopf-Sill discloses all the claimed structural elements and the elements are capable of performing the intended use. More specifically, the measurable property of the probe is capable of being measured using fluorescence polarization (claim 89), and the probe is capable of having a photoluminescence lifetime as claimed in claim 29, since the rotational correlation time of the unbound probe and the rotational correlation time of the complex depends on the use of the polarized light.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is 571-272-0822. The examiner can normally be reached on M-Sat 11-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A.L.



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PRIMARY EXAMINER
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9/7/07